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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,072

09/15/2006

Mitsuhiro Oshiki

529.46525X00

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20457 7590 04/29/2010  
ANTONELLI, TERRY, STOUT & KRAUS, LLP  
1300 NORTH SEVENTEENTH STREET  
SUITE 1800  
ARLINGTON, VA 22209-3873

EXAMINER

BRUTUS, JOEL F

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

04/29/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/593,072	OSHIKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 3 and 6-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 6-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/30/2010 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 6-9, 12-13, and 18, 20-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al (US Pat: 6,132,373).

Regarding claims 1, 6, Ito et al teach an apparatus for measuring an intima-media thickness of a blood vessel that anticipates the claimed invention. Ito et al further teach data analyzing device for receiving image data and calculating the intima media thickness of the blood vessel according to the image data [see abstract]; the digital data

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includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image [see abstract].

Ito et al teach data analyzing device includes a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image [see abstract]; a calculation device for detecting maximum value and a minimum value from among the luminance values corresponding to a predetermined number of the pixels; calculating the intima media thickness based on the maximum and minimum values [see abstract]. Ito et al teaches in the data analyzing device, a certain part of the image of the blood vessel including parts of the intima, media is extracted as a target part which is a line of pixels extending along the radius of the blood vessel [see column 2 lines 52-57].

Ito et al teach setting device calculates a moving average of the luminance values in the target part and sets a base position between the center of the blood vessel and the position in the vicinity of the inner intima wall of the blood vessel within the target part of the image [see column 2 lines 52-55]. A thickness calculation device that includes one to five detection devices for detecting maximum and minimum values of luminance [see column 3 lines 39-54].

Ito also teach adopting a composite thickness of the tunica intima and media i.e., an intima-media thickness (hereinafter referred to as an "IMT") of a carotid arteries as an index of judgment of arterial sclerosis has been studied in the world. Above all, a method of imaging a carotid artery using an ultrasound system, and measuring the IMT

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using an ultrasonic image for the purpose of diagnosis is attracting attention [see column 1 lines 20-25].

Ito et al teach a data analyzing device for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. The digital image data includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image. The data analyzing device includes:

a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image, on the basis of a moving average of the luminance values; and a calculation device for detecting a maximum value and a minimum value from among the luminance values respectively corresponding to a predetermined number of the pixels arranged from the base position toward a position of an outer adventitial wall on the image, and calculating the intima-media thickness on the basis of the maximum value and the minimum value [see abstract].

Regarding claim 20, all other limitations are taught as set forth by the above teaching.

Ito et al teaches calculation device for calculating a difference between a value representing the position of an inner intrimal wall and a value representing the position of an inner advential wall, thereby obtaining the intima media thickness [see column 4 lines 1-3]. Adventitia also known as lunica externa and it is shown in fig 2. Measuring

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location of the border between the intima and media (the outer intimal wall of the inner medial wall), and the location of the border between the media and adventitia (outer media wall or the inner adventitial wall) [see column 9 lines 1-5]. Measuring location of the border is in fact measuring distance between boundaries in the blood vessel (emphasis added).

Regarding claims 3, 7-9, 12-13, 18, all other limitations are taught as set forth by the above teaching.

Ito et al teach the largest peak value is observed at a point indicating a position on the adventitia (lunica externa) and a second peak indicates a position on the intima [see fig 6C and column 9 lines 45-63]; two points Xa and Xb are regarded as points indicating the locations of inner adventitial wall and inner intimal wall [see column 9 lines 55-60]. An algorithm to calculate inner intima and adventitia walls [see column 9 lines 64-67]; In fig 8-9, axis of abscissa indicates positions of pixels arranged along the x axis from a start position of measurement, the axis indicates luminance values observed in an image [see column 10 lines 1-5]. Image data composed of m pixels ranging from the first pixel to the m-th pixel is extracted [see column 10 lines 12-15].

Plotting points of luminance values observed in the extracted image data, data composed of 50 pixels arranged along the X axis is extracted [see column 10 lines 20-23]; in order words a threshold value range of 50 pixels is extracted. An average value of luminance values is calculated in units of 20 pixels from the start position (first pixel and also consider as the reference point) [see fig 6B, column 10 lines 24-27];

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Ito et al teach a difference of the latest average value is calculated and determines whether the difference exceeds a predetermined value or fall below [see column 10 lines 28-33]; comparing peak value luminance to determine the locations of intima and externa. The luminance with largest peak value indicates the location of the externa [see column 10 lines 40-60]. The position or a position at which a decrease in the luminance value becomes equal to or smaller than DI [see FIG 9b] indicates the location of intimal wall [see column 11 lines 11-15].

Moving average value of luminance is calculated in units of 20 pixels from the start position of measurements; determine whether difference exceeds predetermined luminance value; the pixel having the largest luminance is in the region of adventia [see column 10 lines 45-60 and figs 9A-6]. A change in tissular density occurring on the border between the tunica media adventitial is not large; distance resolution of 0.1 mm [see column 11 lines 25-35]. IMT values exceeding 1.1 mm may be colored in red and thus distinguished as a domain and an examiner collects IMT value with an evaluation table to be printed out; a line indicating an IMT of 1.1 mm may be drawn as a reference and a domain of IMT values exceeding 1.1 mm may be colored [see column 15 lines 1-10].

Regarding claims 21-22 and 24, all the limitations are taught as set forth above by Ito et al.

Ito et al 373 teach data analyzing device for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the

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received digital image data which includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image [see abstract].

Ito et al teach data analyzing device includes a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image, on the basis of a moving average of the luminance values [see abstract].

Ito et al teach a calculation device for detecting a maximum value and a minimum value from among the luminance values respectively corresponding to a predetermined number of the pixels arranged from the base position toward a position of an outer adventitial wall on the image, and calculating the intima-media thickness on the basis of the maximum value and the minimum value [see abstract].

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10-11, 15-17, 19 and 23, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat: 6,132,373) in view of Ito et al (US Pat: 5,353,220).



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Regarding claims 10-11, all other limitations are taught as set forth by the above teaching.

Ito et al 373" don't mention binarization process

However, Ito et al 220" teach display data of red and data of blue showing a state of a flow of blood flow with binarization process [see column 3 lines 15-24].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Ito et al 220" with Ito et al 373" by using binarization process; for accuracy purposes.

Regarding claims 15, 23, all other limitations are taught as set forth by the above teaching.

Ito et al 373" don't specifically disclose three dimensional image data.

However, Ito et al 220" disclose a color three dimensional Doppler image data; a flow in a certain blood vessel is adopted as the object [see column 2 lines 55-60], displaying a 3D color Doppler image by respective color reconstructed [see column 3 lines 6-8].

Therefore, one with ordinary skill in the art would have been motivated to combine the Two Ito references by using the teachings of Ito et al to obtain the tunica intima; for the purpose of measuring IMT more accurately and easily.

Regarding claims 16-17, all other limitations are taught as set forth by the above teaching.

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Ito et al 373" disclose ultrasonic probe to emit waves to the common carotid that are reflected more greatly from the region of the intima [see column 8 lines 10-16]. The region reflecting ultrasonic more greatly appears as a high- luminance area in an ultrasonic image on the display screen of the ultrasonic apparatus [see column 8 lines 13-15]; a change in luminance is measured in a direction in which a blood vessel is traversed, whereby intima media thickness can be measured [see column 8 lines 17-20].

Ito et al 373" don't teach an image reconstruction unit.

However, Ito et al 220" disclose extracted profile points are arranged so as to reconstruct three dimensional images [see column 3 lines 1-5].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Ito et al 373" with Ito et al 220" by using three dimensional; in order to increase visualization.

Regarding claim 19, all other limitations are taught as set forth above.

Ito et al 373" don't mention marking the extracted region on the display unit.

However, Ito et al 220" use different colors to mark a blood parameter in a display screen [see column 1 lines 35-50].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by marking the extracted region; in order to increase visualization.

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6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat: 6,132,373) in view of Sano (US Pat: 5,615,680).

Regarding claim 14, all other limitations are taught as set forth above.

Ito et al 373" don't teach a signal processing having a filter.

However, Sano et al teach a low pass filter [see column 6 lines 25-30, lines 50-55] and a signal processor [see column 6 lines 13] and signal processing section [see fig 1].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references; for the purpose of eliminating artifacts or noise in the image; thereby enhancing signal to noise ratio.

### ***Response to Arguments***

7. Applicant's arguments filed 3/30/2010 have been fully considered but they are not persuasive..

Applicant argues that the Ito reference doesn't teach setting means which set reference points of the tunica intima and tunica externa; and determine thickness based on reference points.

Examiner disagrees because Ito teaches a data analyzing device for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. The digital image data includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image. The data analyzing device includes: a setting device for setting a

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base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image, on the basis of a moving average of the luminance values; and a calculation device for detecting a maximum value and a minimum value from among the luminance values respectively corresponding to a predetermined number of the pixels arranged from the base position toward a position of an outer adventitial wall on the image, and calculating the intima-media thickness on the basis of the maximum value and the minimum value [see abstract].

So the setting device that is within the data analyzing device is used to set the reference points of the tunica interna and externa (inherently) (emphasis added). Ito reference makes any calculations based on reference points since the setting device within the data analyzer, sets a base position (value, number, etc..) which is the reference points or values (emphasis added).

Applicant also argues that Ito doesn't teach calculating any distances and thickness based on reference points.

Examiner disagrees because Ito reference makes any calculations based on reference points since the setting device within the data analyzer, sets a base position (value, number, etc..) which is the reference points or values (emphasis added).

Ito further teaches An IMT may be calculated by merely calculating a difference between the data items of the location of the inner intimal wall and inner adventitial wall, if it is allowed to measure the IMT roughly. However, for realizing the distance resolution of 0.1 mm, the IMT must be accurately calculated with the smallest error. Changes in

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the locations of the inner intimal wall and inner adventitial wall relative to the Z-axis direction are expressed with regression curves  $f_i(Z)$  and  $f_c(Z)$  in units of a predetermined range of pixels. An IMT is calculated based on a difference between points [ $f_i(Z_0)$  to  $f_i(Z_c)$  or  $f_c(Z_0)$  to  $f_c(Z_c)$ ] on the regression curves associated with each point (for example  $Z_0$  to  $Z_c$ ) on the Z axis indicating the range of pixels.

### ***Conclusion***

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768